

Full Text PA-97-009

OSTEOPOROSIS AND FRACTURES IN MEN

NIH GUIDE, Volume 25, Number 39, November 15, 1996

PA NUMBER: PA-96-009

P.T. 34

Keywords:

0715031

National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Institute on Aging

National Institute of Diabetes and Digestive and Kidney Diseases

National Institute of Dental Research

National Institute of Environmental Health Sciences

National Institute of Nursing Research

PURPOSE

This initiative invites applications directed to the study of the basic biology, epidemiology, prevention and treatment of osteoporosis and osteoporosis-related fractures in men.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Osteoporosis and Fractures in Men, is related to the priority areas of diabetes and chronic disabling conditions and special population objectives. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0 or Summary Report: Stock No. 017-001-11473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Foreign institutions or organizations in foreign countries are not eligible for First Independent Research Support Transitions (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The support mechanisms for grants in this area will be the individual investigator-initiated research project grant (R01) and the First Independent Research Support and Transition (FIRST) (R29) Award.

Applicants or collaborators from institutions that have a General Clinical Research Center (GCRC) funded by the National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director should be included with the application.

RESEARCH OBJECTIVES

Background

This Program Announcement is intended to address the under-representation of men in studies of osteoporosis. Although 50-year-old white males have about a 13 percent lifetime risk of fractures of the hip, spine or wrist, the etiology and pathogenesis of osteoporosis in males has received little research attention. Men are now much more likely to live into their eighth and ninth decade than 20 years ago. As other causes of early mortality in men are reduced, there is a need to focus on the chronic disabling conditions that will limit independent life in elderly men.

Males are about a decade behind females in the manifestation of osteoporosis and osteoporotic fractures. This has been attributed to a higher peak bone mass at maturity and a more gradual diminution in sex steroid influence in aging males. At each age the rate of hip fracture in men is about 50 percent that in women. While this is true in the United States and Northern Europe, in other parts of the world the hip fracture rates are similar or even greater in men. It has been estimated that 1/3 of hip fractures worldwide are in men.

Therefore hip fractures in men are an important and underscrutinized area of public health. With the decline in premature cardiovascular mortality in males, fractures later in life are becoming an increasingly important cause of morbidity and mortality in older men.

An Annotated Bibliography on Osteoporosis in Men is available from the National Osteoporosis and Related Bone Diseases National Resource Center (phone 202-223- 0344)

Scope

The objective of this PA is to encourage and promote new and innovative research and approaches to elucidate the basic biology, epidemiology, prevention and treatment of osteoporosis and osteoporosis-related fractures in men. For the purposes of this PA skeletal includes craniofacial bone. The following are examples of research topics that are appropriate for this PA; however, they are not to be considered as exclusive or limiting:

- o Examine skeletal developmental differences in males and females
- o Investigate biomechanical and structural differences in males and females of different races and ethnic groups that may illuminate the etiology of fracture risk
- o Determine the risk factors for osteoporosis and fractures in men
- o Elucidate the etiologic factors in osteoporosis in men
- o Determine the calcium and vitamin requirements for optimal bone growth, development and maintenance in men
- o Characterize the differences in the non-gonadal endocrine skeletal regulatory mechanisms in men and women
- o Determine the prevalence of hypogonadism in men and its role in the etiology of osteoporosis
- o Develop population based data sources for the prevalence of low bone mass in males

The areas of interest listed above include bone are not in any order of priority. They are only suggested examples of areas of research to consider. Applicants are encouraged to propose other areas that are related to the objectives and scope of this PA.

INCLUSION OF MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

The inclusion of women is usually standard terminology for all grants and contracts: however, due to the specific subject of this program announcement, osteoporosis and fractures in men, the inclusion of women is not applicable. However, the inclusion of minorities remains relevant.

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minority in Study Populations), which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 5/95) and will be accepted at the standard application deadlines as indicated in the application kit. Applications kits are available at most institutional offices of sponsored research and may be obtained from the Grants Information Office, Office of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: ASKNIH@odrockm1.od.nih.gov.

The title and number of the program announcement must be typed in Section 2 on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

DIVISION OF RESEARCH GRANTS
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the DRG. Incomplete applications will be returned to the applicant without further consideration.

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by an appropriate peer review group convened in accordance with NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of all applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

- o scientific, technical, or medical significance and originality of proposed research;
- o appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- o qualifications and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research;
- o availability of the resources necessary to perform the research;

- o appropriateness of the proposed budget and duration in relation to the proposed research; and
- o adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

The Initial review group will also examine the provisions for the protection of human subjects and animal welfare and the safety of the research environment.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to NIAMS, NIA, NIDDK, NIDR, NIEHS, or NINR. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program relevance and balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

For scientific programmatic inquiries contact:

Joan A. McGowan, Ph.D.
Bone Diseases Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS-43E
45 Center Drive, MSC 4500
Bethesda, Maryland 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543

E-mail: joan_mcgowan@nih.gov

Sherry Sherman, Ph.D.

Geriatrics Program

National Institute on Aging

Gateway Building, Suite 3E327

7201 Wisconsin Avenue, MSC 9205

Bethesda, MD 20892-9205

Telephone: (301) 496-1033

FAX: (301) 402-1784

Email: ShermanS@gw.nia.nih.gov

Ronald N. Margolis, Ph.D.

Chief, Endocrinology Section

Division of Diabetes, Endocrinology and Metabolic Diseases

National Institute of Diabetes and Digestive and Kidney Diseases

Building 45, Room 5AN-12J

45 CENTER DR

Bethesda, MD 20892-6600

Telephone: (301) 594-8819

FAX: (301) 480-3503

Email: rm76f@nih.gov

Linda A. Thomas, Ph.D.

Director, Craniofacial Development and Disorders Program

National Institute of Dental Research

45 Center Drive, Room 4AN24J

Bethesda, MD 20892-6402

Telephone: (301) 594-2425

FAX: (301) 480-8138

E-mail: THOMASL@DE45.NIDR.NIH.GOV

Annette Kirshner, Ph.D.

Bone Metabolism Program

National Institute of Environmental Health Sciences

Box 12233, MD 3-03

Research Triangle Park, North Carolina 27709

Office (919) 541-0488
Fax (919) 541-2843
e-mail: kirshner@niehs.nih.gov

Laura James, PhD, RN
Division of Extramural Activities
National Institute of Nursing Research
Building 45, 3AN-12
Bethesda, MD 20892-6300
Telephone: (301) 594-5959
FAX: (301) 480-8260
Email: Ljames@ep.ninr.nih.gov

Direct inquiries regarding fiscal matters to:

Vicki Maurer
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS-49A
45 Center Drive, MSC 4500
Bethesda, Maryland 20892-6500
Telephone: (301) 594-3504
FAX: (301) 480-4543
E-mail: vicki_maurer@nih.gov

Joseph Ellis
Grants and Contracts Management Office
National Institute on Aging
Gateway Building, Suite 2N212
7201 Wisconsin Avenue, MSC 9205
Bethesda, MD 20892-9205
Telephone: (301) 496-1472
FAX: (301) 402-3672
Email: EllisJ@gw.nia.nih.gov

Kim Law
Grants Management Specialist

Building 45, Room 6AS-49A
National Institute of Diabetes and Digestive and Kidney Diseases
45 CENTER DR
BETHESDA, MD 20892-6600
Telephone: (301) 594-8869

Martin R. Rubinstein
National Institute of Dental Research
45 Center Drive, Room 4AN44A
Bethesda, MD 20892-6402
Telephone (301)594-4800
FAX: (301) 480-480-8301
E-mail: Martin.Rubinstein@NIH.GOV

David Mineo
Chief, Grants Management Branch
National Institute of Environmental Health Sciences
Box 12233, MD 2-01
Research Triangle Park, North Carolina 27709
Office (919) 541-7628
Fax (919) 541-2860
e-mail: mineo@niehs.nih.gov

Jeff Carow
Grants and Contracts Management Branch
National Institute of Nursing Research
Building 45, Room 3AN-32
Bethesda, MD 20892-6301
Telephone: (301) 594-5074
FAX: (301) 480-8256
Email: JCAROW@ep.ninr.nih.gov

AUTHORITY AND REGULATIONS

Awards made in this program are described in the Catalog of Federal Domestic Assistance No. 93.846, 93.847, 93.866, 93.121, 93.113, 93.361. Awards will be made under the authority of the Public Health

Service Act, Title III, Section 301 and Title IV, Part A (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grant policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

[Return to PA Index](#)

[Return to NIH Guide Main Index](#)